# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

OMEROS CORPORATION,	)
Plaintiff,	)
v.	) C.A. No. 17-799 (RGA)
SANDOZ INC.,	)
Defendant.	)
OMEROS CORPORATION,	)
Plaintiff,	)
v.	) C.A. No. 17-803 (RGA)
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	) )
Defendants.	)

## [PROROSIAD] SCHEDULING ORDER

This to day of October, 2017, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

#### IT IS ORDERED that:

- 1. Consolidation.
- a. Plaintiff's Proposal: These actions are consolidated for all purposes and all papers shall be filed in Civil Action No. 17-779-RGA.

b. Defendants' Proposal: These actions are consolidated for purposes of fact discovery and expert discovery and all papers shall be filed in Civil Action No. 17-779-RGA.

- 2. <u>Rule 26(a)(1) Initial Disclosures</u>. The parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) on or before **November 6**, 2017.
- 3. <u>Joinder of Other Parties and Amendment of Pleadings</u>. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **June 1, 2018**.

#### 4. <u>Discovery</u>.

- a. <u>Service</u>. The parties consent to service by email, in accordance with Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure. The parties agree that service on any party by email shall be made on both local and national counsel of that party.
- b. <u>Initial disclosures of custodians, data sources, and notice of issues.</u>

  The parties' initial disclosures of custodians, noncustodial data sources, and notice of issues pursuant to Section 3 of this Court's Default Standard shall occur no later than **November 6**, 2017.
- c. <u>Initial disclosure of asserted patents and accused products</u>. Plaintiff's identification of the accused products, asserted patents, and production of the file histories pursuant to paragraph 4(a) of this Court's Default Standard no later than **November 6**, 2017.
- d. <u>Production of ANDA</u>. Defendants shall produce a copy of their Abbreviated New Drug Application and any other core technical documents, if any, pursuant to paragraph 4(b) of this Court's Default Standard no later than **November 6, 2017**. Defendants

shall produce their ANDA in the eCTD file format in which it was submitted to the FDA.

Defendants shall also produce a second copy of the ANDA in corresponding TIFF images of the FDA documents consistent with the provisions of the Court's Default Standard.<sup>1</sup>

- e. <u>Initial claim chart</u>. Plaintiff shall produce an initial claim chart to Defendant pursuant to paragraph 4(c) of this Court's Default Standard no later than **December** 22, 2017.
- f. <u>Invalidity contentions</u>. Defendants shall produce their initial invalidity contentions and invalidating prior art references pursuant to paragraph 4(d) of this Court's Default Standard no later than **January 31, 2018**.
- g. <u>Discovery from the Par Litigation.</u> Plaintiff shall produce all documents, things, and discovery material produced by Omeros during the fact discovery period to the defendants in *Omeros Inc. v. Par Sterile Products, LLC and Par Pharms., Inc.* no later than **January 17, 2018**.
- h. <u>Discovery Cut Off.</u> All fact discovery in this case shall be initiated so that it will be completed on or before **August 31, 2018**.
- i. <u>Document Production</u>. Document production shall be substantially complete by May 4, 2018.
- j. <u>Requests for Admission</u>. Omeros is permitted a maximum of 70 requests for admission, with a maximum of 35 to be directed towards each Defendant (*i.e.*, 35 requests for admission directed to Sandoz, and 35 requests for admission directed to Lupin).

Plaintiff also agrees that all portions of its NDA that are produced will be provided in the eCTD file format in which they were submitted to the FDA, if available, along with a second copy of the NDA documents in corresponding TIFF images of the FDA documents consistent with the provisions of the Court's Default Standard.

Defendants are entitled to a maximum of 36 joint requests for admission to be directed to Omeros. Each defendant is entitled to an additional 17 individual requests for admission to be directed to Omeros. This limitation does not apply to requests for admission related to authentication of documents.

k. <u>Interrogatories</u>. Omeros is permitted a maximum of 24 interrogatories, with a maximum of 12 interrogatories to be directed to each Defendant (*i.e.*, a maximum of 12 interrogatories directed to Sandoz and a maximum of 12 interrogatories directed to Lupin). Defendants are permitted a maximum of 12 joint interrogatories directed towards Omeros. Each Defendant is also permitted an additional 6 individual interrogatories directed towards Omeros.

### l. <u>Depositions</u>.

<u>Limitation on Hours for Deposition Discovery of Fact</u>

Witnesses for Parties. Lupin and Sandoz are entitled to take a joint seven hour deposition of each listed inventor on any asserted patent. In addition, Defendants together may take a combined total of 49 hours of testimony by deposition upon oral examination of other Omeros fact witnesses other than inventors, so long as no deposition of any single witness exceeds 7 hours. If an inventor is also a corporate designee, the deposition in his or her corporate capacity will run concurrently with any deposition in the inventor's personal capacity. Where it believes good causes exists, Omeros reserves the right to move to shorten the deposition of any Omeros fact witness who was deposed during the *Omeros Inc. v. Par Sterile Products and Par Pharms., Inc.* litigation, other than an inventor, to less than 7 hours. Omeros is entitled to take 42 hours of testimony by deposition upon oral examination of fact witnesses from Sandoz and 42 hours of testimony by deposition testimony upon oral examination of fact witnesses from Lupin. To the

extent that English is not a deponent's native language and a translator or interpreter is used to facilitate his/her testimony, all applicable limitations shall be increased by a factor of 1.5.

(officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement of the parties, and the parties will make good faith efforts to select deposition locations that are convenient for both witnesses and counsel. Employees of Defendants, who are located in the United States, and employees of Plaintiff, who are located in the United States, will be deposed at a location near his or her place of employment unless the parties agree otherwise. In the event of the need for depositions of Defendants' or Plaintiff's employees, who are located outside the United States, the parties will meet and confer and try to reach agreement as to the location of those depositions.

m. <u>Discovery and Communications with Expert Witnesses.</u>

Communications between and among experts for the same party shall not be discoverable, except to the extent that experts rely on facts or information supplied by another expert in support of his or her opinions and the information is otherwise discoverable under Federal Rule of Civil Procedure 26.

n. <u>Discovery Matters and Disputes Relating to Protective Orders.</u>

Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than forty-eight hours prior to the conference/argument, the party

seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than twenty-four hours prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining the party's reasons for its opposition. Should any document(s) be filed under seal, a courtesy copy of the sealed document(s) must be provided to the Court within one hour of e-filing the document(s).

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

5. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within forty-five days from the date of this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 4(n) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

6. <u>Papers Filed Under Seal</u>. When filing papers under seal, counsel shall deliver to the Clerk an original and one copy of the papers. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

- 7. <u>Courtesy Copies</u>. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits, etc.). This provision also applies to papers filed under seal.
- 8. <u>Claim Construction Issue Identification</u>. On or before **February 16, 2018**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **March 16, 2018**. The parties' Joint Claim Construction Chart, in Word or WordPerfect format, shall be e-mailed simultaneously with filing to rga\_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.
- 9. <u>Claim Construction Briefing</u>. The Plaintiff shall serve, but not file, its opening brief, not to exceed 20 pages, on **April 13, 2018**. The Defendants shall serve, but not file, their answering brief, not to exceed 30 pages, on **May 11, 2018**. The Plaintiff shall serve, but not file, its reply brief, not to exceed 20 pages, on **June 1, 2018**. The Defendants shall serve, but not file, their sur-reply brief, not to exceed 10 pages, on **June 22, 2018**. No later than **June 26, 2018**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste

their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

#### JOINT CLAIM CONSTRUCTION BRIEF

- I. Agreed-Upon Constructions
- II. Disputed Constructions
  - A. [TERM 1]
    - 1. Plaintiff's Opening Position
    - 2. Defendants' Answering Position
    - 3. Plaintiff's Reply Position
    - 4. Defendants' Sur-Reply Position
  - B. [TERM 2]
    - 1. Plaintiff's Opening Position
    - 2. Defendants' Answering Position
    - 3. Plaintiff's Reply Position
    - 4. Defendants' Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

10. Hearing on Claim Construction. Beginning at 1:00 mon in late

July 2018, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours.

#### 11. <u>Disclosure of Expert Testimony.</u>

- a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before November 2, 2018. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before December 5, 2018. Reply expert reports from the party with the initial burden of proof are due on or before December 19, 2018. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before February 15, 2019.
- b. <u>Objections to Expert Testimony</u>. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion, fully briefed by both parties and submitted as part of the pre-trial submissions made by the parties under paragraph 12, *infra*, unless otherwise ordered by the Court.
- 12. <u>Applications by Motion</u>. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.
- Rule 16(e) final pretrial conference in Court with counsel beginning at 9004. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5:00 p.m. on the third business day before the date of the final pretrial conference. Unless

otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

- 14. Motions in Limine. Motions in limine shall not be separately filed. All in limine requests and responses thereto shall be set forth in the proposed pretrial order. [If the actions against Lupin and Sandoz are consolidated for all purposes, including trial, Omeros is entitled to three in limine requests directed at Defendants and the Defendants are entitled to a maximum of three common in limine requests directed at Omeros. If the actions against Lupin and Sandoz are not consolidated for purposes of trial, Omeros is entitled to a maximum of three in limine requests against each Defendant and each Defendant is entitled to direct three in limine requests at Omeros.] The in limine request and any response shall contain the authorities relied upon; each in limine request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the in limine request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on in limine requests, unless otherwise permitted by the Court.
- 15. <u>Trial</u>. This matter is scheduled for a [Plaintiff's and Defendant Sandoz's Proposal: 21 hour; Lupin's Proposal: 28 hour] bench trial beginning at 8:30 on May b in late-May, 2019, with the subsequent trial days beginning at 8:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.
- 16. <u>ADR Process</u>. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

17. <u>Statement Regarding Applicability of the Court's "Default Standard for Discovery, Including Discovery of Electronically Stored Information ('ESI')" ("the Default Standard")</u>. The Default Standard shall apply in this case, with the following exceptions:

a. Section (1)(d)(ii) is modified to provide that with respect to information generated on or after July 23, 2015, the parties are not required to include any such information in privilege logs.

b. The timing of disclosures in Sections 4(a)-4(d) shall be in accordance with the dates in Paragraphs 4(a)-4(d) of this Order.

c. Section 5(b)(ii) is modified to provide that email should be preserved, but need not be searched or produced for the first forty-five days following the exchange of initial disclosures pursuant to paragraph 3 of this Court's Default Standard. During that period, the parties will negotiate in good faith to prepare a stipulation governing the production of email that will be presented to the Court.

d. Section 5(d) is modified to provide that Excel and Access files need not be produced in native format to the extent that redaction of privileged or work product material is necessary. If the receiving party determines that production of such a document in non-native format significantly impairs the legibility, functionality, or intelligibility of the document, the parties agree to meet and confer in good faith in an attempt to resolve the dispute. If resolution cannot be reached, the receiving party retains the right to request relief from the Court pursuant to Section 3(m) above.

The Honorable/Richard G. Andrews